Optimized culture of bone marrow-derived human mesenchymal stem cells in a closed system bioreactor

Published: 07-03-2013
Last updated: 26-04-2024

Research will focus on improving and optimizing the cell culture process in a dedicated bioreactor system. The aim of the development is a closed system that can replace current cell culture practice to better guarantee the quality of the cultured...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON41349

Source
ToetsingOnline

Brief title
Optimized culture of bone marrow derived mesenchymal stem cells

Condition

- Bone and joint therapeutic procedures

Synonym
Total hip replacement

Research involving
Human

Sponsors and support

Primary sponsor: Xpand Biotechnology BV
Source(s) of monetary or material Support: Materiaal dat nodig is voor de procedure wordt verstrekt door Xpand Biotechnology B.V. Xpand Biotechnologie ontvangt onder andere

subsidie van de EU (onder het FP7 platform) voor de ontwikkeling van de technologie.

Intervention

Keyword: Bioreactor, Bone marrow, Cell culture

Outcome measures

Primary outcome

Experiments leading to optimized cell culture.

Secondary outcome

Not applicable

Study description

Background summary

Human adult bone marrow-derived stem cells (hMSCs) are currently being investigated as a potential treatment for various afflictions. The use of these cells is being investigated for, among others, steroid-resistant Graft versus Host disease and cartilage or bone defects. The current procedure for production of these cells is very labor-intensive and, because of the open nature of the procedure, there is a significant risk of contamination. The development of a closed system for the safe and easy expansion of these MSCs is important to be able to produce these cells on a larger, therapeutic scale.

Study objective

Research will focus on improving and optimizing the cell culture process in a dedicated bioreactor system. The aim of the development is a closed system that can replace current cell culture practice to better guarantee the quality of the cultured cells. To this end Xpand Biotechnology examines, for example, medium components and composition, culture substrates and environmental parameters such as oxygen tension. Together with academic partners we will look at different application areas and the corresponding quality controls

Study design

Patients that will receive a cementen hip prothesis will be asked to participate. If the patient agrees, a bone marrow biopsy will be taken from the

femoral head during the hip replacement surgery.

Study burden and risks

The risks related to taking a bone marrow biopsy are negligible and, since patients are anesthetized for surgery already, discomfort for participating patients is minimal.

Contacts

Public
Xpand Biotechnology BV

Professor Bronkhorstlaan 10, geb 48
Bilthoven 3723 MB
NL
Scientific
Xpand Biotechnology BV

Professor Bronkhorstlaan 10, geb 48
Bilthoven 3723 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Scheduled for total cemented hip replacement surgery

Exclusion criteria

Radiation of biopsy area

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2013
Enrollment:	208
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41885.100.12